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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,545	01/23/2002	Jarl Wikberg	1808.0010002	6521

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EXAMINER
KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,545	WIKBERG ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-139* is/are pending in the application.

4a) Of the above claim(s) *76-128 and 135-139* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-75 and 129-134* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *54-139* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/387,805* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *0302* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the paper filed 8/27/03 is acknowledged. The traversal is on the ground(s) that the search burden is not undue because: 1) the inventions are not unrelated, with classification being the same and database text search being similar, and 2) there are not a large number (not >10) of sequences to be searched and the receptor subtypes share the same ligand(s). This is not found persuasive because, for the first issue, even though classification is the same, structure is not. Different structure searches are required for each sequence. This is also true for text searching since the different proteins have different names; and, it is noted that art searching is not only for anticipatory references but also those which would render the invention obvious. The broad language in the claims (*e.g.*, 95% identity) further enlarges the search required for each invention. For the second issue, in MPEP 803.04 directed to nucleotide sequences, the Commissioner authorized a partial waiver of restriction practice, allowing the examination of up to ten sequences. This waiver was issued in 1996. Since then, the nucleic acid and protein databases that must be searched for each of the independent and distinct sequence claimed herein have multiplied many fold in size, such that it is now burdensome to search more than a single sequence in an application. Further, the waiver allowed, but did not require the Examiner to search ten sequences.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because of the following informality: on page 81, line 8, it appears that reference to "seq. I.D. no. 10" is in error, since MC-2 DNA is described as being SEQ ID NO:15, and SEQ ID NO.10 is a partial sequence that shares some sequence identity.

Appropriate correction is required.

Claim Objections

Claim 72 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 72 is broader than the claim from which it depends.

Claim 130 is objected to for including non-elected subject matter. See section (c).

Claim Interpretation

The term "homology" used in the claims is being interpreted as meaning "identity" for purposes of calculating what % of the sequence is identical.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 54-74 and 129-134 are rejected under the judicially created doctrine of double patenting over claims 1-28 of U. S. Patent No. 6,448,032 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The patent claims purified DNA encoding amino acids 1-325 of SEQ ID NO:16 or encoding the MSH receptor encoded by the DNA clone in Deposit No. DSM 8440, vector, host cell and polypeptide encoded. The claims of the instant application are broader, encompassing a DNA which hybridizes to the complement of nucleotides 616-1590 of SEQ ID NO:15 (*i.e.*, a sequences which encodes amino acids 1-325 of SEQ ID NO:16) or a DNA 95% identical to the

hybridizing DNA, vector, host cell, method of making the vector and host cell and polypeptide. The species claims of the patent anticipate the genus claims of the application.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 54-67, 68(c) and (f), 69 and 72 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility.

The claims are drawn to DNAs not identical to the coding region of SEQ ID NO:15 or which encode a polypeptide not identical to the SEQ ID NO:16. The specification asserts that such DNAs (subsequences) may be used to identify other DNA fragments or sequences or the original DNA from which it is derived (p. 13, line 15, through p. 14, line 13). However, this is circular reasoning to say that a DNA derived from another DNA may be used to identify the original DNA. Further, this could be true of DNAs in general and does not provide a substantial or specific utility. DNAs which encode SEQ ID NO:16, the MC2 receptor do have utility.

While claim 68 has species which do have utility, see sections (a), (b), (d), and (e) of the claim, that is, the DNA comprising at least bases 616-1590 of SEQ ID NO:16 or which encodes a polypeptide of at least amino acids 1-325 of SEQ ID NO:16, sections (c) and (f) do not.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54-67, 68(c) and (f), 69 and 72 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. DNAs which do not encode the disclosed MSH receptor are merely tools for discovery which require significant further experimentation to use them in a specific and substantial manner.

Claims 129-134 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide which has the sequence of at least amino acids 1-325 of SEQ ID NO:16, including a polypeptide which is encoded by a DNA (i) comprising the nucleotide sequence of SEDQ ID NO:15 or bases 616-1590 (*i.e.*, the coding region) of SEQ ID NO:15 or (ii) encoding the MSHR (melanocyte stimulating hormone receptor) amino acid sequence encoded by the genomic clone contained in DSM Deposit No. 8440 or (iii) encoding at least amino acids 1-325 of SEQ ID NO:16, does not reasonably provide enablement for a polypeptide not identical to at least amino acids 1-325 SEQ ID NO:16. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

SEQ ID NO:16 is a MSHR, called MC2R, with function described in the specification. Claims 129-134 are drawn to polypeptides not identical to SEQ ID NO:16. Claims 129-134 require no function. There is no guidance how to use polypeptides which do not bind MSH. The specification discloses 2 complete melanocortin receptors, however, the specification does not teach which amino acids are necessary to form the MSH ligand binding site or the region providing the three dimensional conformation to allow binding at that site, let alone which amino acids affect affinity. There are no MSH receptors disclosed in the prior art such that the skilled artisan could interpolate from the structure/function relationship of one to another. Even if the binding site were identifiable, one would not be able to reasonably predict which amino acids could be altered such that the polypeptide had a Ki less than 10nM for NDP-MSH as required by claim 134. It is noted that Mountjoy et al. (Science 257:1248, 28 Aug. 1992, cited by Applicants #AT8), which is <u>not</u> prior art, discloses a MSH receptor that is *not* the MC2R receptor of the

instant application, yet which meets the functional requirements of claim 134 (p.1249, col. 1, first full sentence).

Further, MSH receptors are G protein-coupled receptors (p.3, lines 9-15, and paragraph beginning p. 5, line 25), which means that receptor of SEQ ID NO:16 is a protein with 7 transmembrane regions and, typically, 4 extracellular domains. Binding of ligands may occur extracellularly or in a pocket formed by the transmembrane domains (cited by Applicants #AT13), but which domain(s) is involved in binding is not disclosed. Little or no guidance beyond the mere presentation of sequence data has been provided to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (*e.g.*, by amino acid substitutions or deletions), and the nature and extent of the changes that can be made in these positions. It is unpredictable if a polypeptide which does not have a sequence identical to SEQ ID NO:16 would function as a MC2R as disclosed in the instant specification. For these reasons, it would require undue experimentation to make and use a representative number of final species consistent with the scope of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54, 56-61, 68, 129 and 133 and dependent claims 55, 62-67, 69-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 133 is indefinite because a polypeptide cannot comprise a polypeptide (lines 2-3). A polypeptide can comprise an amino acid sequence. This rejection could be obviated by using language such as, 'said first polypeptide comprises the amino acid sequence of said purified polypeptide of claim 130.'

The metes and bounds of claims 54, 56-61, 68, 129 are not clear because the meaning the term "homology" is vague and indefinite. The specification does not provide a limiting definition of the term (*eg.* p. 17, line 33-p. 18. line 6) and the accepted meaning of "homology" in biological term s is "having a common origin." Reeck et al. (1987, Cell, 50 :667, cited by

Applicants #AR10) explain that it is "a concept of quality... a type of relationship between two or more things. Thus amino acids or nucleotide sequences are either homologous or they are not. They cannot exhibit a particular "level of homology" or "percent homology."" A more appropriate term is "identity" which is accepted as having an art-recognized meaning for comparision of nucleic acid or protein sequences.

Conclusion

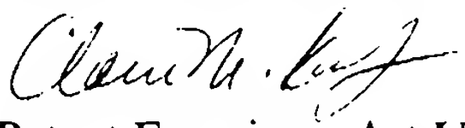
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 872-9306. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

November 3, 2003